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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,736	02/04/2004	David Knaack	2004367-0034	5581
24280 7590 02/22/2010 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER JAGOE, DONNA A				
ART UNIT		PAPER NUMBER		
1619				
NOTIFICATION DATE		DELIVERY MODE		
02/22/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary

Application No.

10/771,736

Applicant(s)

KNAACK ET AL.

Examiner

Donna Jagoe

Art Unit

1619

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-31 and 112-118 is/are pending in the application.
- 4a) Of the above claim(s) 113-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-31 and 112 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date ____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2009 has been entered.

Claims 1-5, 7-31 and 112-118 are pending in this application.

Claims 113-118 are withdrawn.

Election/Restrictions

Newly submitted claims 113-118 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant was presented with a restriction in the office action dated June 26, 2007 wherein the optionally hydroxylated biomolecules selected from polysaccharides, lipids or phospholipids were not elected (group II invention).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 113-118 are withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-31 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Posnansky U.S. Patent No. 2,882,249, Boyce et al. U.S. Patent No. 6,123,731 and Bruin (Makromol. Chem. Rapid Commun. 9, 589-594, 1988) (U).

Posnansky teach the formation of polyurethane with cross-linked bridges (column 2, lines 30-40) by the reaction between a polyisocyanate such as diisocyanate and hydroxy containing monobasic fatty acids (column 1, lines 15-21). It teaches the formation of inter alia, solvent resistant putties (column 2, lines 52-53). Addressing instant claim 5 Posnansky teaches m-tolylene diisocyanate (an alternate chemical name for toluene diisocyanate) as an example of a polyisocyanate that can be employed to make the polyurethane matrix (column 4, lines 54-55). Addressing instant claim 112, drawn to the biodegradable polyurethane composite comprising the combination of polyisocyanate with a biomolecule (non hydroxylated), Example 1, column 6 bridging to column 7, teaches linseed oil (not hydroxylated) combined with isocyanate.

It does not teach the addition of a reinforcement embedded in the matrix selected from bone and bone substitutes such as calcium carbonate.

Boyce et al. teach that the use of autograft bone, allograft bone or xenograft bone is well known in both human and veterinary medicine (column 1, lines 15-30) and teach the use of said osteoimplants combined with reinforcing particle, fiber, fillers and bone growth inducing substances (column 2, lines 13-17), for example, bioabsorbable polymers (column 4, lines 35-36). Boyce et al. further teach the incorporation of bioactive agents such as antimicrobials, sugars, amino acids, peptides, vitamins, endocrine tissue or tissue fragments, hormones, polymer cell scaffolds with

parenchymal cells, etc. (column 4, line 51 to column 5, line 31). It does not specifically recite lecithin, lectins, growth factors, immunosuppressives and chemoattractants; however Boyce et al. recites that other bioactive agents can be incorporated into the implant. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. The express suggestion to substitute one equivalent for another need not be present to render the substitution obvious.

Bruin et al. teach L-lysine based di (or tri)isocyanates for the synthesis of biodegradable synthetic polyurethanes with applications such as artificial skin (introduction), formed by a reaction with lysine diisocyanate, (a polyisocyanate). The prepolymers were cross-linked using 2,6 diisocyanatohexate (page 591). Bruin et al. employs the same biodegradable synthetic polyurethanes, reacted with lysine diisocyanate, for developing a vascular frame, meniscus prosthesis, artificial skin and nerve guide (see abstract) and Boyce provides motivation to employ bone or bone substitutes with the biodegradable polyurethane scaffold with active agents. Bruin et al. disclose Gamma caprolactone (page 590 and 591) which is a species of polycaprolactone. Regarding instant claims 9 and 10 drawn to further incorporation of bioactive agent, Boyce et al. teach the incorporation of suitable biostatic/biocidal agents (column 4, lines 17-50). The reference is silent regarding amount of reinforcement in the composite; however, the idea of combining reinforcement to composite material was recognized in the art as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the

polyurethane composite that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The instant claims are drawn to polyurethane wet compressive strength of between 3 MPa and 100 MPa. Bruin et al. teach a MPa tensile strength of between 8 to 40 MPa (see table 1, page 593). Bruin et al. fail to disclose the MPa tensile strength of from 50 to 100 MPa, wet tensile strength, creep rate, degradation rate, maximum shear strength, maximum resolved compressive strength and maximum resolved tensile strength, however, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Response to Arguments

Applicant asserts that Posansky teaches polyacidesters, not fatty acids. In response, Posansky teaches that the starting materials of the invention are hydroxy-containing monobasic fatty acids and may be either saturated or unsaturated and may be either naturally occurring or artificially synthesized and are treated with

polyisocyanate (column 3, lines 4-10). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Gunatillake reference is removed as detailed *supra*.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./
Examiner
Art Unit 1619

February 12, 2009